REMARKS

A substitute Abstract is provided. The specification has been amended to clarify a subject heading. No new matter is believed to be added to the application by this Amendment.

Status of the Claims

Claims 1-12 are pending in the application. The amendments to claims 1-8 clarify the language of these claims. The amendments to claims 1, 3, 4, 5, 7 and 8 do not narrow the scope of these claims. Support for the amendments to claims 2 and 6 can be found at page 4 of the specification. Support for claims 9-12 can be found at page 16 of the specification.

Rejection Under 35 U.S.C. 112, Second Paragraph

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph as being indefinite. Applicant traverses this rejection and respectfully requests reconsideration and withdrawal thereof.

The claims as amended do not recite "conventional auxiliaries" or "conventional methods". Indolent agents, recited in claims 4 and 8, are discussed at page 3, line 18 of the specification. Additionally, the amended claims set forth that the amount of active ingredients are greater than 0%. As a result, the claims as amended are clear, definite and have full antecedent basis. Accordingly, this rejection is overcome and withdrawal thereof is indicated.

Double Patenting Rejection Over Kim '521

Claims 1 and 2 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of Kim '521 (U.S. Patent No. 6,071,521). Applicant traverses this rejection and respectfully requests reconsideration and withdrawal thereof.

Kim '521 has the same inventorship as the instant application and therefore the inventor has intimate knowledge of this reference.

In Kim '521, the ingredients were extracted at 60°C or at higher temperature. For example, examples 3-5 of Kim '521 extracts mixtures containing Pulsatillae Radix at temperatures of 60°C or 80°C. See Kim '521 at column 4.

In contrast, the present invention extracts Pulsatillae Radix containing compositions at temperatures below 60°C. When these extracts are lyophilized, the resulting composition shows enhanced stability and superior activities on tumor cell lines. That is, the present invention shows unexpected results over Kim '521.

Evidence of these unexpected results can be found in the examples of the specifications. Comparative Examples 1-3 are prepared according to the technology of Kim '521, which performs extractions at 60°C or 80°C. In comparison, examples 1-9 of the invention all perform extraction below 60°C. When the antitumor

effects are compared, the extracts of the invention show superior performance. Typically, when Example 1 and Comparative Example 1 were tested on rats, the control group of Comparative Example 1 showed remarkably higher rat mortality up to the sixteenth day. See page 12 of the specification.

Additionally, the test results show that the lyophilized powders of the invention have enhanced stability. This stability results in injectable solutions being preferable after two years of storage. In comparison, the comparative technology of Kim '521 showed settling at one month and turbidity at three months. See page 18 of the specification.

In the Office Action the Examiner asserts that "product-by-process claims are not considered to make the claim patentably distinct unless Applicant can demonstrate a difference between the referenced composition and the claimed composition." However, Applicants have demonstrated that the ingredients of the invention are extremely sensitive to temperature and may be degraded during extraction and storage, and extraction at 60°C or higher yields a product having lower activities on tumor cell lines and lower stability. As a result, the composition of the invention is clearly superior to that of Kim '521.

As has been shown, the teachings of Kim '521 would not motivate a person having ordinary skill in the art to produce a claimed embodiment of the present invention where the product is

extracted at less than 60°C. Thus, a *prima facie* case of obviousness has not been made. Further, unexpected results rebut any obviousness that can be alleged and distinguish the claims of the invention over Kim '521.

Accordingly, this rejection is overcome and withdrawal thereof is indicated.

Rejection Under 35 U.S.C. 102(b)/103(a) Over Kim '502

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated or in the alternative under 35 U.S.C. 103(a) as being obvious over Kim '502 (EP 0416502 A1). Claims 5-8 are rejected under 35 U.S.C. 103(a) as being obvious over Kim '502. Applicant traverses these rejections and respectfully requests reconsideration and withdrawal thereof.

Kim '502 has the same inventorship as the instant application. As a result, the inventor has intimate knowledge of this reference.

Similar to Kim '521 discussed above, Kim '502 pertains to pharmaceutical compositions prepared from mixtures containing Pulsatillae Radix. Similarly, mixtures containing Pulsatillae Radix were extracted at 60°C or at 80°C. See examples 3-5 at page 4 of Kim '502. In fact, examples 3-5 of Kim '521 are identical to examples 3-5 of Kim '502.

As a result, all of the distinctions and evidence presented traversing the rejection of Kim '521 or equally applicable to Kim '502. These distinctions and evidence are set forth above.

As a result, there is no teaching or suggestion in Kim '502 for the preparation of pharmaceutical compositions from Pulsatillae Radix by extractions at below 60°C. Therefore Kim '502 fails to anticipate the present invention and additionally fails to render the present invention *prima facie* obvious. Further, even if it assumed *arguendo* that Kim '502 suggests the present invention, unexpected results fully rebut any obviousness that can be alleged. These unexpected results compared with the examples of the invention to examples 3-5 of both Kim '521 and Kim '502 have been discussed above.

Accordingly, this rejection is overcome and withdrawal thereof is indicated.

Correspondence

The Examiner is respectfully requested to address all future correspondence in connection with this application to Joseph A. Kolasch at the address below.

Conclusion

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully

requested to contact Robert E. Goozner, Ph.D. (Reg. No. 42,593) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Attached hereto is a marked-up version of the changes made to the application by this Amendment.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a three (3)month extension of time for filing a reply in connection with the present application, and the required fee of $460.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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Attachment: Version with Markings to Show Changes Made

Rev. 02 23 02

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

Please replace the heading on page 1, line 11, with --Description of the Related Art--.

IN THE CLAIMS:

The claims have been amended as follows:

1. (Amended) A pharmaceutical antitumor composition [having antitumor activity] which comprises:

extract of at least one of Pulsatillae Radix or extract of Ulmaceae cortex as active ingredients(s), prepared by extracting 0-100wt% of powdered Pulsatillae Radix and 0-100wt% of powdered Ulmaceae cortex, the amount of Pulsatillae Radix and Ulmaceae cortex being greater than 0%, in a solvent at [the] a temperature of below 60°C[,]; and

filtering and lyophilizing the extract.[, and then admixing the lyophilized powder with conventional auxiliaries, or admixing the above extracted solution with auxiliaries, then filtering and lyophilizing the mixture, and then formulating the lyophilized powder to a pharmaceutical preparation by a conventional method used in the pharmaceutics.]

2. (Amended) A pharmaceutical antitumor composition comprising: [having antitumor activity prepared by extracting 0-100wt% of

powdered Pulsatillae Radix and 0-100wt% of powdered Ulmaceae Cortex, provided that the content of Pulsatillae Radix and Ulmaceae Cortex is]

over 30wt%[,] of extract of at least one of Pulsatillae Radix or Ulmaceae as active ingredient(s); and [one ore more ingredients selected from 0-70% of powdered]

below 70wt% extract of Ginseng Radix [and 0-70wt% of] and/or Glycyrrhizae Radix as auxiliary ingredient(s), prepared by extracting 30-70 wt% of powdered Pulsatillae Radix and powdered Ulmaceae cortex, the amount of the powdered Pulsatillae Radix and the powdered Ulmaceae cortex being greater than 0%, and by extracting 30-70wt% of powdered Ginseng Radix and 30-70% of powdered Glycyrrhizae Radix, the amount of the powdered Ginseng Radix and the powdered Glycyrrhizae Radix being greater than 0%, in a solvent at [the] a temperature of below 60°C, filtering and lyophilizing the extract[, and admixing the lyophilized powder with conventional auxiliaries, or admixing the extracted solution with auxiliaries, filtering and lyophilizing the mixture, and then formulating the lyophilized powder to a pharmaceutical preparation by a conventional method used in the pharmaceutics].

3. (Amended) The pharmaceutical composition according to claims 1 or 2, wherein the solvent is [selected from] water, alcohol, acetone, ethyl acetate [and] or mixtures thereof and the

composition is formulated [in a form selected from] as powder, granule, tablet, capsule, injectable powder [and] or ointment.

4. (Amended) The pharmaceutical composition according to claims 1 or 2, wherein the auxiliaries are one or more selected from the group consisting of diluent, binding agent, disintegrator, preservative, indolent, isotonic agent and lubricant.

5. (Amended) A process for the preparation of a pharmaceutical antitumor composition, which comprises: [having antitumor activity comprising]

extracting 0-100wt% of powdered Pulsatillae Radix and 0-100wt% of powdered Ulmaceae cortex, the amount of the powdered Pulsatillae Radix and the powdered Ulmaceae cortex being greater than 0%, in a solvent at [the] a temperature of below 60°C[,];

filtering; and

lyophilizing the extract[, and admixing the lyophilized powder with conventional auxiliaries, or admixing the above extracted solution with conventional auxiliaries, then filtering and lyophilizing the mixture, and then formulating the lyophilized powder to a pharmaceutical preparation by a conventional method used in the pharmaceutics].

6. (Amended) A process for the preparation of a pharmaceutical antitumor composition [having antitumor activity] comprising over 30wt% of extract of Pulsatillae Radix and/or extract of Ulmaceae cortex as active ingredient(s) and less than 70wt% of extract of Ginseng Radix and/or Glycyrrhizae Radix as auxiliary ingredients(s), which comprises:

extracting [0-100wt%] 30-70wt% of powdered Pulsatillae Radix and [0-100wt%] 30-70wt% of powdered Ulmaceae cortex, the amount of Pulsatillae Radix and Ulmaceae cortex being greater than 0%; [provided that the content of Pulsatillae Radix and Ulmaceae Cortex is over 30wt%, and one ore more ingredients selected from 0-70wt% of]

extracting 30-70wt% of powdered Ginseng Radix and [0-70wt%] 30-70 wt% of powdered Glycyrrhizae Radix, the amount of Ginseng Radix and Glycyrrhizae Radix being greater than 0%, in a solvent at [the] a temperature of below 60°C[,];

filtering; and

lyophilizing the extract[, and admixing the lyophilized powder with conventional auxiliaries, or admixing the above extracted solution with auxiliaries, then filtering and lyophilizing the mixture, and then formulating the lyophilized powder to a pharmaceutical preparation by a conventional method used in the pharmaceutics].

7. (Amended) The process according to claims 5 or 6, wherein the solvent is [selected from] water, alcohol, acetone, ethyl acetate [and] or mixtures thereof and the composition is formulated [in a form selected from] as powder, granule, tablet, capsule, injectable powder [and] or ointment.

8. (Amended) The process according to claims 5 or 6, wherein the extract is mixed with at least one auxiliary selected from the group consisting of [auxiliaries are one or more selected from] diluent, binding agent, disintegrator, preservative, indolent, isotonic agent and lubricant.

Claims 9-12 have been added.